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EXAMINER

ALVESTEFFER, STEPHEN D

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2175

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/808,142	Applicant(s) STEIN ET AL.	
	Examiner Stephen Alvesteffer	Art Unit 2175	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21,23-40 and 42-92 is/are pending in the application.
- 4a) Of the above claim(s) 44,48-57 and 65-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21,23-40,42,43,45-47,58-64 and 82-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20100119</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is responsive to the Request for Continued Examination (RCE) filed March 31, 2010. Claims 1, 46, 47, 58, 82, and 92 are amended. Claims 22 and 41 were previously cancelled. Claims 1, 44, 46-48, 57, 58, 65, 76, 82, and 92 are independent. Claims 1-21, 23-40, and 42-92 remain pending. Of the pending claims, claims 44, 48-57 and 65-81 were previously withdrawn.

The Information Disclosure Statement (IDS) filed January 19, 2010 was considered by the examiner.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 24 March 2003. It is noted, however, that applicant has not filed a certified copy of the 0306746.9 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 46, 47, 58, 82, and 92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

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contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The independent claims were amended to narrow the definition of “skipping one or more nodes” to “refraining from executing one or more intervening nodes between a last executed node and a next executed node along the currently traversed patient care pathway in response to input indicating one or more nodes to be traversed from the healthcare practitioner during traversal of the currently traversed patient care pathway”. However, this narrower definition is not supported in the instant disclosure. Of “skipping one or more nodes”, the instant specification paragraph [0131] only states, *“In some cases, it may also be possible for the clinical practitioner to skip certain nodes 426 in a workflow 424, this functionality being incorporated into the definition of the node”*.

Applicant is requested to either delete the unsupported limitations or direct the examiner to the relevant portions of the disclosure where the limitations are supported. In the interest of advancing prosecution and pending response from Applicant, this Office Action is presented under the assumption that the newly introduced amendments are fully supported in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 11-16, 20, 21, 23, 24, 35-37, 39-43, 45-47, 58-64, 82-85, and 87-92 rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae et al. (hereinafter Macrae), United States Patent 5,786,816, Usitalo et al. (hereinafter Usitalo), United States Patent Application Publication 2002/0099679, and Mitchell et al. (hereinafter Mitchell), United States Patent 6,684,188.

Regarding claim 1, Macrae substantially teaches a programmed computer comprising a processor configured to assist a healthcare practitioner in diagnosing and treating patients by interacting with the healthcare practitioner during progression through a stored clinical best practice workflow comprised of a plurality of interlinked steps (see Macrae column 1 lines 6-11; *"The present invention relates to providing graphic medical healthcare plans (protocols), and in particular a graphic user interface,*

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for developing, viewing and implementing medical healthcare plans”), the programmed computer comprising:

a page including a map for assisting the healthcare practitioner to navigate the stored clinical best practice workflow, the map comprising a plurality of patient care pathways, each patient care pathway conforming with best practice guidelines and comprising a series of a plurality of interlinked nodes, wherein each node in the series has a unique relationship with a respective step in the stored best practice workflow (see Macrae Figure 1 and column 6 lines 26-31; *"In Flow Chart view 11, the process flow begins with a Start node, enters into the first Order nodes, and flows out to Result nodes. After the results are entered, the process flow continues on to a Flow Control node where the next step in the treatment is determined"*);

a data entry module for entering clinical data relating to a particular selected node, the data entry module comprising display means for displaying, within a portion of the page, a predetermined data entry request and a response made by the healthcare practitioner to the request (see Macrae Figure 3 and column 6 line 53 through column 7 line 8; *"a user can start the flow, enter order result into the various nodes, and move through the flow as the treatment progresses using the Flow Chart view instead of the Chart view if the user desires"*);

data recording means for storing the response, made by the healthcare practitioner to the request, in a data record (see Macrae column 2 lines 44-55; *"Processing means controls the storage means, input means and the display means in response to stored programs and input data"*);

pathway means arranged to use the response of the healthcare practitioner stored in the data record to graphically indicate a suggested node to traverse next within the stored best practice workflow (see Macrae column 7 lines 50-60; “*The Flow Control node contains rules that select a branch at a decision point in a template or plan, and estimates of the likelihood of branching down given paths. During patient charting, the Flow Control node suggests the next step to the healthcare provider based on the rules and the results entered in Result nodes*”; see also Macrae column 13 lines 20-30; “*These connections indicate possible paths or branches a plan takes during delivery, and are illustrated as arrows*”);

a navigation module arranged to enable the healthcare practitioner to choose the node to traverse next independently of the node suggested by the pathway means, the navigation module being further arranged to permit the healthcare practitioner to traverse a route across the map that skips one or more nodes from the series of the plurality of interlinked nodes representing a currently traversed patient care pathway, wherein the skipping comprises refraining from executing one or more intervening nodes between a last executed node and a next executed node along the currently traversed patient care pathway in response to input indicating one or more nodes to be traversed from the healthcare practitioner during traversal of the currently traversed patient care pathway (Usitalo, addressed below);

graphical means for graphically representing in the page a route traversed by the healthcare practitioner across the map (see Macrae column 19 lines 36-44; “*When a user takes a branch down a path that leads to a Plan node in the patient's chart, the*

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Plan node is highlighted in both the Flow Chart and the patient Chart views”; see also Macrae column 6 line 53 through column 7 line 8; “a user can start the flow, enter order result into the various nodes, and move through the flow as the treatment progresses using the Flow Chart view instead of the Chart view if the user desires. Color-coding on the nodes show which ones are completed and which are in progress”); and

Electronic Patient Record Management System (EPRMS) management means for communicating with an EPRMS and obtaining and presenting details of a selected electronic patient record in a portion of the page (Mitchell, addressed below).

Macrae does not explicitly teach navigation means arranged to enable the healthcare practitioner to choose the node to traverse next independently of the node suggested by the pathway means, the navigation means being further arranged to permit the healthcare practitioner to traverse a route across the map that skips one or more nodes from the series of the plurality of interlinked nodes representing a currently traversed patient care pathway, wherein the skipping comprises refraining from executing one or more intervening nodes between a last executed node and a next executed node along the currently traversed patient care pathway in response to input indicating one or more nodes to be traversed from the healthcare practitioner during traversal of the currently traversed patient care pathway. Macrae teaches that the healthcare practitioner may choose a branch to traverse next independently of the branch suggested by the pathway means (see Macrae column 19 lines 56-60; “*To force the plan to branch down a specific path, regardless of the result values and the flow control rules, a user opens the right-most active Flow Control node, select the rule*

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governing the desired path, and click the Execute button. The plan will branch down the specified path"; see also Macrae column 12 lines 36-40; "The Flow Control node contains the rules that determine which set of orders are followed. Flow Control nodes are connected to one or more Order nodes. However, only one of the Order nodes will be executed"). This effectively skips the nodes of the branch that was not selected by the healthcare practitioner, but does not allow the healthcare practitioner to refrain from executing one or more intervening nodes between a last executed node and a next executed node along the currently traversed patient care pathway. However, allowing a user to skip nodes along an expert system workflow was not new or novel in the art at the time the instant invention was made. For example, Usitalo teaches a computer implemented system for the production of medical records that allows an healthcare practitioner ("expert") to skip over certain question nodes along the suggested pathway (see Usitalo paragraph [0053], "*a user is guided in a step-by step approach by the interactive system 1 to one or more solutions to the identifiable problem... the interactive system 1 allows the user to "skip" steps or work in any order the user desires... Since some steps in the process may be trivial to a user with experience, it is contemplated that the user be allowed to "skip" these steps. Nonetheless, the system 1 will encourage all users to following the appropriate step-by-step template provided by the system.* "). It would have been obvious for one of ordinary skill in the art at the time the invention was made, having the prior art disclosures of Macrae and Usitalo laid before him, to allow users to skip over certain workflow steps as taught by Usitalo along a clinical pathway as described by Macrae in order to allow healthcare practitioners to

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personalize the workflow and also to skip steps that they find trivial (see Usitalo paragraph [0053], "*The purpose of allowing user's to skip steps is to allow user's... to somewhat personalize their workflow. Since some steps in the process may be trivial to a user with experience, it is contemplated that the user be allowed to "skip" these steps.*").

Macrae/Usitalo does not explicitly disclose Electronic Patient Record Management System (EPRMS) management means for communicating with an EPRMS and obtaining and presenting details of a selected electronic patient record in a portion of the page. Mitchell teaches a computer implemented system for the production of medical records that stores and retrieves patient data in an electronic medical record database (see Mitchell Figure 42, depicting an example of data recalled in database for analysis; see also Mitchell column 8 lines 39-56, "*It is still a further object of the invention to provide increased efficiency by producing documents in an electronic format... There is a great deal of talk and interest in the "electronic medical record".... One more advantage of this invention is that because the document can be edited by the original producer in real time, it can immediately be saved or transmitted in electronic format. Thus this invention will allow users to move much closer to the dream of the "paperless office".*"; see also Mitchell column 31 lines 30-39, "*According to this invention, pieces of data are recorded in variables. The variables 244 can be thought of as receptacles which contain individual pieces of data as the value 270. These individual pieces of data can be imported from or exported to a data base. Each variable 596 in the CaD program can correspond to a field 597 in a database. Once copied to a*

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database, this information can be sorted, filtered or queried. Various analyses can be performed and suitable reports printed.”). It would have been obvious to one of ordinary skill in the art at the time the invention was made to store and retrieve patient record information electronically as taught by Mitchell in the invention of Macrae/Usitalo to provide increased efficiency by producing documents in an electronic format.

Regarding claim 2, Macrae/Usitalo/Mitchell teaches that the plurality of patient care pathways represent a complete stored clinical best practice workflow on a single page (see Macrae Figure 1).

Regarding claim 3, Macrae/Usitalo/Mitchell teaches that each node represents an action, decision or result within the stored clinical best practice workflow (see Macrae column 7 lines 27-34; *“There are five kinds of nodes: Start, Order, Results, Flow Control, and Exit”*).

Regarding claim 4, Macrae/Usitalo/Mitchell teaches that the data entry module comprises presentation means for presenting data relevant to a location of the selected node and selection means for enabling the healthcare practitioner to select at least some of that data (see Macrae column 11 line 28; *“Or1 node is selected by clicking it”*).

Regarding claim 5, Macrae/Usitalo/Mitchell teaches every limitation of claim 5 except that the presentation means comprises a plurality of drop-down lists of location-specific information. Although Macrae does not teach using a plurality of drop-down lists to edit location-specific information, Macrae does disclose the use of drop-down lists (see Macrae Figure 21 and column 14 lines 40-46; *“For this example, click the At Probability drop-down arrow button 213 and select 10 as the percentage”*). Drop-down

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lists are a standard user interface component for use in data entry. Macrae makes use of drop-down lists in some instances. It would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to use a plurality of drop-down lists to edit location-specific information.

Regarding claim 6, Macrae/Usitalo/Mitchell teaches that the data entry module is arranged to use the entered data at a first node to determine further information required at a second node, linked to the first node (see Macrae column 18 lines 48-53; *“Each time an order result is entered, the rules in the Flow Control node are evaluated to see if enough information is available to branch to the next step in the plan. When all of the order results specified in a rule are entered, the rule is evaluated. If the rule is satisfied, the rule will become active and take the plan down the corresponding path”*).

Regarding claim 7, Macrae/Usitalo/Mitchell teaches updating means for updating any information related to the step in the stored clinical best practice workflow with entered data (see Macrae column 9 lines 57 and 58; *“Edit button 119 edits the detail of the selected order, including the order's result values when clicking”*).

Regarding claim 11, Macrae/Usitalo/Mitchell teaches analyzing means for analyzing the entered data and generating a list of actions associated therewith and listing means for listing the list of associated actions to the healthcare practitioner adjacent the interlinked nodes (see Macrae Figure 2, showing the interlinked nodes and a list of actions with associated cost analysis at the bottom).

Regarding claim 12, Macrae/Usitalo/Mitchell teaches that at least some of the nodes include information means providing a graphical indication that concealed clinical

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information relating to the step in the stored best practice workflow associated with that node is available for presentation on the page, the information means being arranged to reveal the concealed clinical information on selective interaction with the nodes by the healthcare practitioner (see Macrae column 6 lines 38-42; *“The Zoom view is used to see the details inside the nodes of the template. Each node is magnified or expanded to show information contained within, as well as the relationships between the nodes in the flow chart. A user can use this view to examine the entire template”*).

Regarding claim 13, Macrae/Usitalo/Mitchell teaches that the graphical indication is a graphical icon (see Macrae Figure 2).

Regarding claim 14, Macrae/Usitalo/Mitchell teaches that the information means is arranged to provide a plurality of different levels of detail of information, in accordance with a selection made by the healthcare practitioner (see Macrae column 6 lines 38-42; *“The Zoom view is used to see the details inside the nodes of the template. Each node is magnified or expanded to show information contained within, as well as the relationships between the nodes in the flow chart. A user can use this view to examine the entire template”*).

Regarding claim 15, Macrae/Usitalo/Mitchell teaches action list means for generating a list of actions and presenting the same to the healthcare practitioner adjacent the plurality of interlinked nodes, the action list means being arranged to determine the list from analysis of the healthcare practitioner’s navigation through the plurality of interlinked nodes (see Macrae Figure 2, showing the plurality of displayed interlinked nodes and a list of actions with associated cost analysis at the bottom).

Regarding claim 16, Macrae/Usitalo/Mitchell teaches that the action list means is arranged, at the end of traversal of the map, to present the list to the healthcare practitioner with options for the healthcare practitioner to confirm each action, and to determine the list of actions to be implemented from the healthcare practitioner's confirmation (see Macrae Figure 2, showing the plurality of displayed interlinked nodes and a list of actions with associated cost analysis at the bottom).

Regarding claim 20, Macrae/Usitalo/Mitchell teaches a new page linking means for linking a node at the end of a series of a plurality of interlinked nodes within one page to a node within another different page (see Macrae Figure 23 and column 19 lines 45-51; *"When a user charts a patient plan into a Plan node, the previous plan is discontinued and the new plan is started. The view of the new plan will be used to continue charting"*).

Regarding claim 21, Macrae/Usitalo/Mitchell teaches that the new page linking means comprises a graphical icon and selection by the healthcare practitioner comprises interaction between an end-user navigational tool and the icon (see Macrae Figure 23 and column 19 lines 45-51; *"When a user charts a patient plan into a Plan node, the previous plan is discontinued and the new plan is started. The view of the new plan will be used to continue charting"*).

Regarding claim 23, Macrae/Usitalo/Mitchell teaches that the EPRMS management means further comprises population means for populating one or more nodes with at least some of the details of a selected electronic patient record, thereby reducing any required data entry at that node (see Mitchell Figure 42, depicting an

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example of data recalled in database for analysis; see also Mitchell column 8 lines 39-56, *"It is still a further object of the invention to provide increased efficiency by producing documents in an electronic format... There is a great deal of talk and interest in the "electronic medical record".... One more advantage of this invention is that because the document can be edited by the original producer in real time, it can immediately be saved or transmitted in electronic format. Thus this invention will allow users to move much closer to the dream of the "paperless office"."*; see also Mitchell column 31 lines 30-39, *"According to this invention, pieces of data are recorded in variables. The variables 244 can be thought of as receptacles which contain individual pieces of data as the value 270. These individual pieces of data can be imported from or exported to a data base. Each variable 596 in the CaD program can correspond to a field 597 in a database. Once copied to a database, this information can be sorted, filtered or queried. Various analyses can be performed and suitable reports printed."*).

Regarding claim 24, Macrae/Usitalo/Mitchell teaches that the EPRMS management means is arranged to use the details of the selected electronic patient record to determine what information is required at a node from the healthcare practitioner (see Mitchell Figure 42, depicting an example of data recalled in database for analysis; see also Mitchell column 8 lines 39-56, *"It is still a further object of the invention to provide increased efficiency by producing documents in an electronic format... There is a great deal of talk and interest in the "electronic medical record".... One more advantage of this invention is that because the document can be edited by the original producer in real time, it can immediately be saved or transmitted in*

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electronic format. Thus this invention will allow users to move much closer to the dream of the "paperless office."; see also Mitchell column 31 lines 30-39, "According to this invention, pieces of data are recorded in variables. The variables 244 can be thought of as receptacles which contain individual pieces of data as the value 270. These individual pieces of data can be imported from or exported to a data base. Each variable 596 in the CaD program can correspond to a field 597 in a database. Once copied to a database, this information can be sorted, filtered or queried. Various analyses can be performed and suitable reports printed.").

Regarding claim 35, Macrae/Usitalo/Mitchell teaches an editing module for editing the nodes on a page, the editing module being arranged to update the stored workflow to reflect any change made to the page (see Macrae Figure 1 and column 6 lines 14-25; *"FIG. 1 illustrates an example of a Template Builder window with an open template"*).

Regarding claim 36, Macrae/Usitalo/Mitchell teaches that the editing module is arranged to enable the healthcare practitioner to add a new node and to specify the contents of the new node (see Macrae Figure 9 and column 8 lines 59-65; *"FIG. 9 illustrates adding an Order node Or1, Result node Re1 and Flow Control node FI1 to a template"*).

Regarding claim 37, Macrae/Usitalo/Mitchell teaches that the editing module is arranged to enable the healthcare practitioner to specify functionality associated with a node (see Macrae column 8 lines 59-65; *"The Order node Or1 contains the physician's orders, such as lab tests, nursing procedures, x-rays, prescriptions, and other kinds of*

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treatments or actions. These generalized orders may be taken from a library and placed in Order node Or1”).

Regarding claim 39, Macrae/Usitalo/Mitchell teaches that the editing module is arranged to enable the healthcare practitioner to control the positioning of the new node within the page and interconnection of the new node to the existing nodes (see Macrae column 6 lines 14-25; *“The template contains a number of graphic elements including: a start node, three triplets of an order node, a result node, a flow control node and an exit node. These graphical elements are positioned in window 10 in order to represent a medical healthcare treatment plan”*).

Regarding claim 40, Macrae/Usitalo/Mitchell teaches recording means for recording the route traversed by the healthcare practitioner across the map (see Macrae column 6 lines 26-31; *“In Flow Chart view 11, the process flow begins with a Start node, enters into the first Order nodes, and flows out to Result nodes. After the results are entered, the process flow continues on to a Flow Control node where the next step in the treatment is determined”*).

Regarding claim 42, Macrae/Usitalo/Mitchell teaches navigation analysis means, wherein information relating to each step in the process is cost quantifiable and the navigation analysis means is arranged to determine a total cost of the route traversed by the healthcare practitioner (see Macrae column 2 lines 26-38; *“it is desirable to provide an apparatus and method for providing a medical healthcare plan which will 1) reduce errors associated with communications between healthcare planners and providers; 2) allow for convenient modification of medical health treatment*

plans; 3) provide costs associated with each step in the medical health treatment plan, as well as the total cost of the medical health treatment plan”).

Regarding claim 43, Macrae/Usitalo/Mitchell teaches that the navigation analysis means is arranged to analyse the performance of the healthcare practitioner through the stored best practice workflow (see Macrae column 6 lines 26-31; *“In Flow Chart view 11, the process flow begins with a Start node, enters into the first Order nodes, and flows out to Result nodes. After the results are entered, the process flow continues on to a Flow Control node where the next step in the treatment is determined”*).

Regarding claim 45, Macrae/Usitalo/Mitchell teaches that the programmed computer provides a user interface to a knowledge base storing the clinical best practice workflow (see Macrae column 2 lines 44-55; *“The display includes a plurality of graphic icon images, stored in the storage location, arranged on the display representing a medical treatment plan”*).

Claim 46 recites a programmed computer having substantially the same limitations as the programmed computer of claim 1. Therefore, claim 46 is rejected under the same rationale.

Claim 47 recites a computer-implemented method having substantially the same limitations as the programmed computer of claim 1. Therefore, claim 47 is rejected under the same rationale.

Regarding claim 58, Macrae/Usitalo/Mitchell teaches a programmed computer comprising a processor configured to assist a healthcare practitioner in diagnosing and

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treating patients by interacting with the healthcare practitioner during progression through a respective centrally-stored version of a clinical best practice workflow comprised of a plurality of interlinked steps (see Macrae column 1 lines 6-11; *"The present invention relates to providing graphic medical healthcare plans (protocols), and in particular a graphic user interface, for developing, viewing and implementing medical healthcare plans"*; see also Macrae column 8 lines 4-11; *"a physician may retrieve a template from the library that addresses a similar condition, modify the template as needed, and start the patient treatment using the modified template"*; see also Macrae column 31 lines 41-65; *"Every user may have their own library or link to a common library shared by others... Library items added at the top level are available to everyone within the network"*), and the programmed computer comprising:

a page including a map for assisting the healthcare practitioner to navigate the respective centrally-stored version of the clinical best practice workflow, the map comprising a plurality of patient care pathways, each comprising a series of a plurality of interlinked nodes, wherein each node in the series has a unique relationship with a respective step in the respective centrally-stored version of the clinical best practice workflow (see Macrae Figure 1 and column 6 lines 26-31; *"In Flow Chart view 11, the process flow begins with a Start node, enters into the first Order nodes, and flows out to Result nodes. After the results are entered, the process flow continues on to a Flow Control node where the next step in the treatment is determined"*);

an editing module for enabling the healthcare practitioner to edit at least some of the nodes on the page (see Macrae Figure 1 and column 6 lines 14-25; *"FIG. 1 illustrates an example of a Template Builder window with an open template"*);

updating means arranged to update the plurality of interlinked steps of the respective centrally-stored version of the clinical best practice workflow with any corresponding changes made to the respective nodes on the page by the healthcare practitioner (see Macrae column 9 lines 57 and 58; *"Edit button 119 edits the detail of the selected order, including the order's result values when clicking"*);

a navigation module arranged to enable the healthcare practitioner to choose the node to traverse next, and to permit the healthcare practitioner to traverse a route across the map that skips one or more nodes from the series of the plurality of interlinked nodes representing a currently traversed patient care pathway, wherein the skipping comprises refraining from executing one or more intervening nodes between a last executed node and a next executed node along the currently traversed patient care pathway in response to input indicating one or more nodes to be traversed from the healthcare practitioner during traversal of the currently traversed patient care pathway (see Usitalo paragraph [0053], *"a user is guided in a step-by step approach by the interactive system 1 to one or more solutions to the identifiable problem... the interactive system 1 allows the user to "skip" steps or work in any order the user desires... Since some steps in the process may be trivial to a user with experience, it is contemplated that the user be allowed to "skip" these steps. Nonetheless, the system 1*

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will encourage all users to following the appropriate step-by-step template provided by the system."); and

Electronic Patient Record Management System (EPRMS) management means for communicating with an EPRMS and obtaining and presenting details of a selected electronic patient record in a portion of the page (see Mitchell Figure 42, depicting an example of data recalled in database for analysis; see also Mitchell column 8 lines 39-56, *"It is still a further object of the invention to provide increased efficiency by producing documents in an electronic format... There is a great deal of talk and interest in the "electronic medical record".... One more advantage of this invention is that because the document can be edited by the original producer in real time, it can immediately be saved or transmitted in electronic format. Thus this invention will allow users to move much closer to the dream of the "paperless office"."; see also Mitchell column 31 lines 30-39, "According to this invention, pieces of data are recorded in variables. The variables 244 can be thought of as receptacles which contain individual pieces of data as the value 270. These individual pieces of data can be imported from or exported to a data base. Each variable 596 in the CaD program can correspond to a field 597 in a database. Once copied to a database, this information can be sorted, filtered or queried. Various analyses can be performed and suitable reports printed.").*

Claims 59-64 recite a programmed computer having substantially the same limitations as the programmed computer of claims 35-39. Therefore, the claims are rejected under the same rationale.

Regarding claim 82, Macrae/Usitalo/Mitchell teaches a computer-implemented method of constructing a graphical user interface for assisting a healthcare professional in diagnosing and treating patients, the computer-implemented method comprising:

collating, using a programmed computer, content regarding a clinical best practice workflow (see Macrae column 7 lines 22-26; *“Before a user can create a template, treatment work flow must be defined; that is, the order in which treatment activities are carried out for a given condition”*);

recording, using a programmed computer, the content in a database as a series of steps of a hierarchically structured clinical best practice workflow (see Macrae column 16 lines 22-30; templates are created and saved);

automatically generating, using a programmed computer, a graphical representation of the hierarchical clinical best practice workflow from the content recorded in the database, which can be used to guide a healthcare practitioner progressively through the clinical best practice workflow (see Macrae column 1 lines 6-11; *“The present invention relates to providing graphic medical healthcare plans (protocols), and in particular a graphic user interface, for developing, viewing and implementing medical healthcare plans”*);

enabling, using a programmed computer, the healthcare practitioner to choose the node to traverse next, and to permit the healthcare practitioner to traverse a route across the map that skips one or more nodes from the series of the plurality of interlinked nodes representing a currently traversed patient care pathway, wherein the skipping comprises refraining from executing one or more intervening nodes between a

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last executed node and a next executed node along the currently traversed patient care pathway in response to input indicating one or more nodes to be traversed from the healthcare practitioner during traversal of the currently traversed patient care pathway (see Usitalo paragraph [0053], "*a user is guided in a step-by step approach by the interactive system 1 to one or more solutions to the identifiable problem... the interactive system 1 allows the user to "skip" steps or work in any order the user desires... Since some steps in the process may be trivial to a user with experience, it is contemplated that the user be allowed to "skip" these steps. Nonetheless, the system 1 will encourage all users to following the appropriate step-by-step template provided by the system.*"); and

communicating, using a programmed computer, with an Electronic Patient Record Management System (EPRMS) to obtain and present details of a selected electronic patient record in a portion of the page (see Mitchell Figure 42, depicting an example of data recalled in database for analysis; see also Mitchell column 8 lines 39-56, "*It is still a further object of the invention to provide increased efficiency by producing documents in an electronic format... There is a great deal of talk and interest in the "electronic medical record".... One more advantage of this invention is that because the document can be edited by the original producer in real time, it can immediately be saved or transmitted in electronic format. Thus this invention will allow users to move much closer to the dream of the "paperless office".*"; see also Mitchell column 31 lines 30-39, "*According to this invention, pieces of data are recorded in variables. The variables 244 can be thought of as receptacles which contain individual*

pieces of data as the value 270. These individual pieces of data can be imported from or exported to a data base. Each variable 596 in the CaD program can correspond to a field 597 in a database. Once copied to a database, this information can be sorted, filtered or queried. Various analyses can be performed and suitable reports printed.”);

wherein the graphical representation comprises a page including a map for assisting the healthcare practitioner to navigate the stored clinical best practice workflow, the map comprising a plurality of patient care pathways, each patient care pathway conforming with best practice guidelines and comprising a series of a plurality of interlinked nodes, wherein each node in the series has a unique relationship with a respective step in the hierarchical clinical best practice workflow structure (see Macrae Figure 1 and column 6 lines 26-31; *"In Flow Chart view 11, the process flow begins with a Start node, enters into the first Order nodes, and flows out to Result nodes. After the results are entered, the process flow continues on to a Flow Control node where the next step in the treatment is determined"*).

Claims 83-85 recite a computer-implemented method having substantially the same limitations as the programmed computer of claim 1. Therefore, the claims are rejected under the same rationale.

Regarding claim 87, Macrae/Usitalo/Mitchell teaches that said clinical information is revealed on the page by selection of the node itself within the programmed computer by the healthcare practitioner (see Macrae Figure 14 and column 10 lines 50-55; *"Double-clicking Results node Re1 presents Result Node detail box 140"*).

Regarding claim 88, Macrae/Usitalo/Mitchell teaches that selective interaction with the node by the healthcare practitioner comprises interaction between an end-user navigational tool and the icon (see Macrae Figure 14 and column 10 lines 50-55; *“Double-clicking Results node Re1 presents Result Node detail box 140”*).

Regarding claim 89, Macrae/Usitalo/Mitchell teaches that the graphical means is arranged to graphically indicate previously executed steps in the best practice workflow to the healthcare practitioner (see Macrae column 19 lines 36-44; *“When a user takes a branch down a path that leads to a Plan node in the patient's chart, the Plan node is highlighted in both the Flow Chart and the patient Chart views”*).

Regarding claim 90, Macrae/Usitalo/Mitchell teaches that previously executed steps in the best practice workflow are graphically indicated to the healthcare practitioner (see Macrae column 19 lines 36-44; *“When a user takes a branch down a path that leads to a Plan node in the patient's chart, the Plan node is highlighted in both the Flow Chart and the patient Chart views”*).

Regarding claim 91, Macrae/Usitalo/Mitchell teaches interacting with a node displaying a graphical indication that concealed clinical information relating to the step in the stored best practice workflow associated with the node is available, thereby revealing the concealed clinical information in use (see Macrae column 9 lines 38-41; *“By double-clicking Order node Or1 in the triplet shown in FIG. 9 or 10. The Order Node Detail dialog box 110 appears showing the list of orders (i.e., content) in Order node Or1”*).

Claim 92 recites a programmed computer having substantially the same limitations as the programmed computer of claim 1. Therefore, claim 92 is rejected under the same rationale.

Claims 8-10, 28-34, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae (5,786,816) *supra*, Usitalo (2002/0099679) *supra*, Mitchell (6,684,188) *supra*, and DeBusk et al. (hereinafter DeBusk), United States Patent 6,314,556.

Regarding claim 8, Macrae/Usitalo/Mitchell teaches every limitation of claim 8 except means for converting the entered data into a classification code representing that data. The use of standard classification codes was well known in the healthcare industry at the time the invention was made. DeBusk mentions the use of standardized codes within his healthcare application (see DeBusk column 13 lines 28-43; “*the Procedure Attributes field 316 is provided which will allow the user to select standardized procedure codes, such as the AMA IC9 code and description, for the procedure to be represented by the pathway*”). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use standardized classification codes in a healthcare application in order to distinctly identify information.

Regarding claim 9, Macrae/Usitalo/Mitchell/DeBusk teaches that the classification code comprises a standard classification code describing a complete range of possible data inputs relevant to the subject of the stored clinical best practice workflow (see DeBusk column 13 lines 28-43).

Regarding claim 10, Macrae/Usitalo/Mitchell/DeBusk teaches that the classification code represents one of the group comprising a diagnosis, a symptom, an action, a treatment and an operative procedure (see DeBusk column 13 lines 28-43).

Regarding claim 28, Macrae/Usitalo/Mitchell/DeBusk teaches searching means for searching an externally accessible knowledge base, the searching means being arranged to convert a selected information topic (see Macrae column 32 lines 37-41; *“The Find Item method 410 allows a client application to search through the library to find all the items that match the specified attributes and search criteria. The method returns a container holding the matching library items, or actually references to the items”*) into a predetermined classification code representing that topic and to transmit that classification code within an information request to the knowledge base for relevant information contained therein (see DeBusk column 13 lines 44-59; *“This function is provided with a database search capability, by the Search button 318, which allows the user to search a pre-configured procedure code database for the appropriate procedure information”*).

Regarding claim 29, Macrae/Usitalo/Mitchell/DeBusk teaches that the classification code comprises a standard classification code describing a complete range of possible data inputs relevant to the subject of the stored best practice workflow (see DeBusk column 13 lines 28-43; *“the Procedure Attributes field 316 is provided which will allow the user to select standardized procedure codes, such as the AMA IC9 code and description, for the procedure to be represented by the pathway”*).

Regarding claim 30, Macrae/Usitalo/Mitchell/DeBusk teaches that the classification code represents one of the group comprising a diagnosis, a symptom, an action, a treatment and an operative procedure (see DeBusk column 13 lines 28-43; *“the Procedure Attributes field 316 is provided which will allow the user to select standardized procedure codes, such as the AMA IC9 code and description, for the procedure to be represented by the pathway”*).

Regarding claim 31, Macrae/Usitalo/Mitchell/DeBusk teaches that the searching means is arranged to receive a response to the information request and display the results of the search to the healthcare practitioner (see Macrae column 32 lines 37-41; *“The Find Item method 410 allows a client application to search through the library to find all the items that match the specified attributes and search criteria. The method returns a container holding the matching library items, or actually references to the items”*).

Regarding claim 32, Macrae/Usitalo/Mitchell/DeBusk teaches that the searching means is arranged to receive a response to the information request and use the response to determine a relevant page of a plurality of pages for display to the healthcare practitioner (see Macrae column 32 lines 37-41).

Regarding claim 33, Macrae/Usitalo/Mitchell/DeBusk teaches that the searching means is arranged to display a plurality of information topics to the healthcare practitioner and to enable selection of at least some of these information topics, each information topic being related to the current node location of the healthcare practitioner within the current page (see Macrae column 32 lines 37-41).

Regarding claim 34, Macrae/Usitalo/Mitchell/DeBusk teaches that the searching means is arranged to enable the healthcare practitioner to enter additional information topics not displayed by the searching means (see Macrae column 32 lines 37-41).

Regarding claim 38, Macrae/Usitalo/Mitchell/DeBusk teaches that the editing module is arranged to enable the healthcare practitioner to add or edit a classification code associated with the contents of a node (see Macrae column 6 lines 14-25; *“FIG. 1 illustrates an example of a Template Builder window with an open template”*, the Template Builder allows users to add any node and the contents of the added node).

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae (5,786,816) *supra*, Usitalo (2002/0099679) *supra*, Mitchell (6,684,188) *supra*, and Balint et al. (hereinafter Balint), United States Patent 5,542,024.

Regarding claim 17, Macrae/Usitalo/Mitchell teaches every limitation of claim 17 except for a note recordal means for recording textual notes generated by the healthcare practitioner relating to a particular node, the note recordal means being arranged to link the note with the particular node such that the stored note is retrievable when the healthcare practitioner has navigated to that particular node. Balint teaches an expert system in which users can record textual notes that will also be visible to other users of the system (see Balint claims 21 and 22; *“means for creating a note data base record to be linked to a currently displayed decision node in the expert system in response to the selection of a write representative icon displayed by said Graphical User Interface”* and *“includes means to add a read representative icon to said Graphical*

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User Interface display whenever one of said note data base records has been linked to the decision node of the knowledge record then being displayed"). It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow textual notes to be attached to workflow nodes in order to provide an intuitive method of knowledge exchange between users of the system.

Regarding claim 18, Macrae/Usitalo/Mitchell/Balint teaches that the note recordal means is arranged to record a variation of the stored clinical best practice workflow at a particular node as determined by the healthcare practitioner (see Balint claims 21 and 22).

Regarding claim 19, Macrae/Usitalo/Mitchell/Balint teaches feedback generation means for converting a note determined by the healthcare practitioner into a transmittable message and for transmitting the message to another healthcare practitioner having access to a version of the programmed computer (see Balint, Claims 21 and 22).

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae (5,786,816) *supra*, Usitalo (2002/0099679) *supra*, Mitchell (6,684,188) *supra*, and Greenberg et al. (hereinafter Greenberg), United States Patent Application Publication 2004/0039602.

Regarding claim 25, Macrae/Usitalo/Mitchell teaches every limitation of claim 25 except referral means for generating a referral message, the referral means being provided at a node and using information associated with the node to populate at least

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some of the referral message on selection by the healthcare practitioner. Greenberg teaches a computerized system that assists a healthcare professional in accessing patient medical record data, following clinical pathway protocols, and entering data (see Greenberg paragraph [0005]; *"the system helps to ensure that the patient is properly evaluated, all pertinent information is gathered, etc. and that all appropriate treatment options are considered. Additionally, patient medical record data is available, and examination data is recorded, at the point of care. Optionally, the system may store a protocol database accessible by the examination and/or treatment modules to guide the clinician through examination and treatment according to predefined protocols. For example, these treatment protocols can be established on the basis of clinical pathways, research protocols, or cost of care"*). Greenberg also teaches that the invention is capable of generating and storing referrals (see Greenberg paragraph [0007]; *"The system is capable of generating medical and related records (collectively, "medical records"), such as examination notes, orders, bills, referral letters, etc., by incorporating relevant data stored by the system into predefined templates, such as Microsoft Word or Excel documents"*). It would have been obvious to one of ordinary skill in the art at the time the invention was made to generation, storing, and accessing of referrals as taught by Greenberg in the invention of Macrae/Usitalo/Mitchell so that all relevant information about a patient is accessible from the same system.

Regarding claim 26, Macrae/Usitalo/Mitchell/Greenberg teaches that the referral means comprises a graphical icon and selection by the healthcare practitioner

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comprises interaction between a user navigational tool and the icon (see Figure 1, Macrae's invention makes extensive use of icons for interaction and navigation).

Regarding claim 27, Macrae/Usitalo/Mitchell/Greenberg teaches that the referral means is arranged to use information obtained from an electronic patient record to populate automatically at least some of the referral message (see Greenberg paragraph [0007]; *"The system is capable of generating medical and related records (collectively, "medical records"), such as examination notes, orders, bills, referral letters, etc., by incorporating relevant data stored by the system into predefined templates, such as Microsoft Word or Excel documents"*).

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae (5,786,816) *supra*, Usitalo (2002/0099679) *supra*, Mitchell (6,684,188) *supra*, and Huyn et al. (hereinafter Huyn), United States Patent Application Publication 2002/0035486.

Regarding claim 86, Macrae/Usitalo/Mitchell teaches every limitation of claim 86 except that the editing module is arranged such that its use by the healthcare practitioner is restricted by permissions. Huyn teaches a computerized clinical questionnaire system that makes use of permissions (see Huyn paragraph [0064]; *"once the user has submitted the response data, he or she cannot modify the data without permission from the questionnaire administrator"*). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use permissions as taught by Huyn to regulate the use of the invention taught by Macrae/Usitalo/Mitchell to prevent unauthorized changes from being made to the system.

Response to Arguments

Regarding the 35 U.S.C. 112, first paragraph rejection of claims 1, 46, 47, 58, 82, and 92, Applicant asserts that the Office has not established by a preponderance of evidence why a person skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. Examiner respectfully disagrees.

Applicant points to MPEP § 2163.04, which states that a “description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption.” However, MPEP § 2163.04 regards cases where it is alleged that the written description does not support the **originally filed** claims.

Concerning cases where new matter is added to the claims in amendment, MPEP § 2163(I)(B) states in part, “*The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed... New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement... newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure... The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.*”

Regarding the examiner's burden of determining adequacy of the written description, MPEP § 2163(II)(A) states in part, *"There is a strong presumption that an adequate written description of the claimed invention is present in the specification **as filed**... however, **with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims.** See MPEP § 714.02 and § 2163.06 ("Applicant should * * * specifically point out the support for any amendments made to the disclosure."); and MPEP § 2163.04 ("If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.")"* (emphasis added)

Therefore, it is maintained that the original disclosure **does not** support the newly added limitations of "wherein the skipping comprises refraining from executing one or more intervening nodes between a last executed node and a next executed node along the currently traversed patient care pathway in response to input indicating one or more nodes to be traversed from the healthcare practitioner during traversal of the currently traversed patient care pathway", as provided in the 35 USC 112 rejection above. Applicant now bears the burden of pointing out where and/or how the originally

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filed disclosure supports the amendments or to delete the unsupported portions of the claims.

Applicant has amended claims 1, 46, 58, and 92 to remove means plus function language in the navigation limitation. Accordingly, the 35 USC 112 second paragraph rejection of the claims is withdrawn.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Sati et al. (US 2005/0203384) Computer assisted system and method for minimal invasive hip, uni knee and total knee replacement

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Alvesteffer whose telephone number is (571)270-1295. The examiner can normally be reached on Monday-Friday 9:30AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, William Bashore can be reached on (571)272-4088. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 2175

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